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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,550	10/31/2003	Susan J. Wong	454311-2232.1	9527

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EXAMINER	
MCGAW, MICHAEL M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,550	WONG ET AL.	
	Examiner	Art Unit	
	Michael M. McGaw	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-160* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

)☐ Notice of References Cited (PTO-892)

)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 123 and 124 drawn to a diagnostic kit comprising WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against a flavivirus.

Group II, claims 9, 14 and 15 drawn to a method of detecting WNV infection in a subject utilizing a WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure.

Group III, claims 10, 14, 15, 19-23, 26-33, 37-40, 44-59, 61-66, 125, drawn to a method of detecting a flavivirus infection in a subject utilizing a WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure that is cross-reactive with antibodies against flavivruses other than WNV.

Group IV, claims 11, 14 and 15 drawn to a method of detecting a protective immune response in a subject utilizing a WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure.

Group V, claim 60, drawn to a method for the transfer of information obtained as a result of carrying out any of the methods of claims 1, 9, 10, 11, 19, 32, 33, 44, or 53. Note that claim 1 is a product claim and therefore there can be no information as a result of carrying out that claim.

Group VI, claim(s) 69-73, drawn to a diagnostic kit comprising WNV NS5 protein, or fragment thereof, having a native conformation or non-

denatured structure where the NS5 protein is reactive with antibodies against WNV and not reactive with antibodies against a flavivirus other than WNV.

Group VII, claim(s) 74, 78, 79, 80-105, 126-128 and 145 drawn to a method of detecting a WNV seropositivity in a subject utilizing a WNV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with antibodies against WNV and not reactive with antibodies against a flavivirus other than WNV.

Group VIII, claim(s) 75, 78, 79 and 105 drawn to a method of detecting a protective immune response in a subject utilizing a WNV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with antibodies against WNV and not reactive with antibodies against a flavivirus other than WNV.

Group IX, claim(s) 106 drawn to a method for discriminating an ongoing WNV infection from a serocoversion to a killed flavivirus vaccine via screening for both anti-E antibodies and anti-NS5 antibodies.

Group X, claim(s) 107 drawn to a method for detecting a recent or ongoing WNV infection via screening for both anti-E antibodies and anti-NS5 antibodies.

Group XI, claim(s) 129-136, 138-141, 146 and 147, drawn to a method of detecting antibody to a serospecific Dengue virus in a subject utilizing a serospecific DENV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with serospecific DENV antibodies and not reactive with antibodies against a flavivirus other than that particular DENV serotype.

Group XII, claim(s) 137, drawn to a diagnostic kit comprising a serospecific DENV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with serospecific DENV antibodies and not reactive with antibodies against other flaviviruses.

Group XIII, claim(s) 142, 143, drawn to a method of determining whether a previously DENV-vaccinated animal recently sustained exposure to DENV using DENV NS5 protein having a native conformation or non-denatured structure where the NS5 protein is reactive with DENV antibodies and not reactive with antibodies against a flavivirus other than DENV.

Group XIV, claims 144, 148, drawn to a method of detecting a flavivrus infection in a subject using a microsphere immunoassay where the microsphere is coupled to a flavivirus NS5 protein having a native conformation or non-denatured structure where each NS5 protein is reactive to said flavivirus but not cross-reactive to other flaviviruses.

Group XV, claims 149-155 and 160, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to flavivirus antigens.

Group XVI, claim 156, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a WNV NS5 antigen with the amino acid sequence of SEQ ID NO. 8.

Group XVII, claim 157, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a DENV NS5 antigen with the amino acid sequence of SEQ ID NO. 10.

Group XVIII, claim 158, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a DENV NS5 antigen with the amino acid sequence of SEQ ID NO. 12.

Group XIX, claim 159, drawn to a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a WNV E glycoprotein antigen with the amino acid sequence of SEQ ID NO. 6.

The Following claims were not grouped:

Claims 12, 13, 16-18, 35, 36, 41-43, 67, 68, 76, 77, 108-122 are improper multiple dependent claims.

There is more than one claim 24 and 25.

There is no claim(s) 34

The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V, IX, X, XVIII appears to be that all relate to the use of WNV E protein, or fragment thereof, having a native conformation or non-denatured structure where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against a flavivirus. Groups VI-VIII, XIII-XVII, XIX-XXI do not require the use of WNV E protein.

However, this technical feature lacks novelty in the art, (see Davis et al., *J. of Virol.*, May 2001, 75(9):4040-47) disclosing the production of WNV envelope (E) protein antigen in the second paragraph on page 4040. Since the special technical feature of group I lacks novelty in the art, any subsequent group lacks unity of invention with the first group.

The special technical feature of group I is considered to WNV envelope (E) protein, or fragment thereof, having a native conformation or non-denatured structure where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against a flavivirus.

The special technical feature of group II is considered to be a method of detecting WNV infection using WNV E protein where the E protein is reactive with antibodies against WNV.

The special technical feature of group III is considered to be a method of detecting flavivirus infection using WNV E protein where the E protein is reactive with antibodies against WNV and cross-reactive with antibodies against a flavivirus.

The special technical feature of group IV is considered to be a method of detecting a protective immune response in a subject using WNV E protein.

The special technical feature of group V is considered to be a method for the transfer of information as a result of carrying out the methods of Groups II-IV.

The special technical feature of group VI is considered to be a WNV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with antibodies against WNV and not reactive with antibodies against a flavivirus other than WNV.

The special technical feature of group VII is considered to be a method of detecting a WNV seropositivity in a subject utilizing a WNV NS5 protein.

The special technical feature of group VIII is considered to be a method of detecting a protective immune response in a subject utilizing a WNV NS5 protein.

The special technical feature of group IX is considered to be a method for discriminating an ongoing WNV infection from a serocoversion to a killed

flavivirus vaccine via screening for both anti-E antibodies and anti-NS5 antibodies.

The special technical feature of group X is considered to be a method for detecting a recent or ongoing WNV infection via screening for both anti-E antibodies and anti-NS5 antibodies.

The special technical feature of group XI is considered to be a method of detecting antibody to a serospecific Dengue virus in a subject utilizing a serospecific DENV NS5 protein where the NS5 protein is reactive with serospecific DENV antibodies and not reactive with antibodies against a flavivirus other than that particular DENV serotype.

The special technical feature of group XII is considered to be a serospecific DENV NS5 protein, or fragment thereof, having a native conformation or non-denatured structure where the NS5 protein is reactive with serospecific DENV antibodies and not reactive with antibodies against other flaviviruses.

The special technical feature of group XIII is considered to be method of determining whether a previously DENV-vaccinated animal recently sustained exposure to DENV using DENV NS5 protein having a native conformation or non-denatured structure where the NS5 protein is reactive with DENV antibodies and not reactive with antibodies against a flavivirus other than DENV.

The special technical feature of group XIV is considered to be a method of detecting a flavivrus infection in a subject using a flavivirus NS5 protein having a native conformation or non-denatured structure where each NS5 protein is reactive to said flavivirus but not cross-reactive to other flaviviruses.

The special technical feature of group XV is considered to be a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to flavivirus antigens.

The special technical feature of group XVI is considered to be a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a WNV NS5 antigen with the amino acid sequence of SEQ ID NO. 8.

The special technical feature of group XVII is considered to be a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a DENV NS5 antigen with the amino acid sequence of SEQ ID NO. 10.

The special technical feature of group XVIII is considered to be a method for carrying out an immunochromatographic test for detecting a flavivirus infection

using a suspension of microspheres coupled to a DENV NS5 antigen with the amino acid sequence of SEQ ID NO. 12.

The special technical feature of group XIX is considered to be a method for carrying out an immunochromatographic test for detecting a flavivirus infection using a suspension of microspheres coupled to a WNV E glycoprotein antigen with the amino acid sequence of SEQ ID NO. 6.

Accordingly, Groups I-XIX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, June 03, 2004

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600